Unidirectional Airflow Smoke Test Protocol

Persons signing as approvers shall have examined the Unidirectional Airflow Protocol. This approval shall signify that testing of operational parameters is adequate to demonstrate that the system meets unidirectional airflow for isolator's requirements.

APPROVALS

Name/Title	Signature	Date
Cert. Mgr.		3-9-2018
Service Mgr.		3-9-2018

Protocol prepared by:

Name HANK RAITH **Signature**

Dept./Organization: CONTAINTECH - CONSULTING **Phone:** 317 753-5312

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FDA guidance (USP <797> references FDA definition of unidirectional airflow)

In situ air pattern analysis should be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. The studies should be well **documented** with **written conclusions**, and include evaluation of the impact of aseptic manipulations (e.g., interventions) and equipment design. **Videotape** or other recording mechanisms have been found to be useful aides in assessing airflow initially as well as facilitating evaluation of subsequent equipment configuration changes.

1.0 SIGNATURE LOG

Persons performing any test or portions of a test, reviewing data, or entering comments on a test page will enter their printed name, their signature, Company and their initials.

Name (Print) & Company	Signature	Initial/Date

Location _____

Serial Number _____

Single _____ Dual _____ Other _____

2.0 Protocol Objective

The objective of this unidirectional airflow smoke testing protocol is to verify that the isolator air handling system provides unidirectional air flow during dynamic compounding conditions in the critical pressing area per FDA and USP <797> definitions. The MIC isolator is designed for the protection of components during the aseptic manipulation based on USP <797> that states "The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins.".

The two elements play a role in creating the aseptic environment are decontamination of components used to produce compounded preparations and providing an ISO class 5 air particulate quality environment in which manipulations occurs. The smoke test protocol does not address decontamination directly however airflow does play a role in the effectiveness of the decontamination process in terms of exposure and residence time on surfaces of non-sterile outside of components in the environment used in compounding.

The MIC airflow design is to enhance the decontamination process as well as meet the definitions of air quality required in the Direct Compounding Area (DCA) described as a critical area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air. Since particulates are generated during the aseptic manipulations from both component surfaces as well the actual manipulations it is important that these particles be removed from the (DCA). Unidirectional airflow is a means of controlling and removing particulate.

FDA guidance and USP <797> use the same definition of unidirectional airflow i.e. Unidirectional flow- An airflow moving in a single direction, in a robust and uniform manner, and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

Particulate control and removal is important in all aseptic isolators. Controlling direction is part of airflow control. There are several methods of determination of direction of airflow with smoke testing being the most subjective. Smoke testing is used as an indicator of the direction of the airflow depends on personnel observation. Individual observation are influenced by location, density of smoke and type of materials used to generate the smoke.

Experience has shown that a properly located video camera ideally not a cell phone inside the isolator produces the most realistic view of a smoke pattern. Filming is an art, get somebody with expertise. Be aware of B.R.A.D[1]: Background, Reflection, Angle and Direction

1.Juan M. Rodríguez,Validation Manager ,Bristol-Myers Squibb, Syracuse, NY

3.0 Responsibilities

Isolator Manufacturer

- Identify intended Direct Compounding Area (DCA). MIC chamber from each side panel and three inches from front and back end panels
- Identify placement of smoke[1] source
- Identify correct placement for camera

Owner – Verify that the individual conducting the smoke test has the following:

- The correct protocol for conducting the test
- Familiar with protocol positing requirements of both smoke source and camera
- Reviewed validated smoke test video
- Confirm certifier has previous experience with horizontal air flow. If not request they contact CTG.
- Verify materials for conducting the dynamic test are available

Certifier – Review the correct protocol for conducting the smoke test including placement of smoke source (9 inches from left end panel, 9 inches off the floor and 9 inches from front panel) and camera. Remember B.R.A.D[1].

- Review video to become familiar with required equipment
- Review protocol and verify correct equipment is available
- Review placement requirements for smoke source, camera

4.0 Testing Devices

All devices used in testing will be documented, and calibrated where appropriate. Information recorded is to include manufacturer, model number and date of calibration or calibration expiration date.

Item	Manufacturer	Model Number	Date of Calibration / Expiration Date	Other	Initials

5.0 Tests Performed

5.1 Particle Counts

Particle counts will be taken in the DCA.

Location	1	2	3	Initials
Counts				

5.2 Smoke Source

5.2.1 Verify the smoke source is in the correct position
5.2.2 Verify smoke source is able to generate a consistent and repeatable source of visible smoke that is
5.2.3 Verify that the smoke source does not generate an excessive amount of smoke that will impact the clarity of the video.
5.2.4 Verify material used to generate smoke **Note** **Titanium tetrachloride effects stainless steel and can deactivate hydrogen peroxide used to reduce bioburden**

5.3 Camera

5.3.1 Verify camera position (Background, Reflection, Angle and Direction)
5.3.2 Verify the area filmed encompasses the DCA

6.0 Specifications and Acceptance Criteria

6.1 Airflow is unidirectional per FDA definition - An airflow moving in a single direction, in a robust and uniform manner, and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.
Acceptance Criteria – Airflow is consistent with FDA definition of unidirectional airflow

6.1.1 The DCA for the MIC chamber from each side panel and three inches from front and back end panels
Acceptance Criteria – testing conducted within DCA

6.2 Verify ISO 5 conditions inside the DCA via particle counts. Sweeping action over and away from the product under dynamic conditions
Acceptance Criteria – Particle count do not exceed ISO class 5

Unidirectional Airflow Smoke Test Protocol Results Summary

Acceptance Criteria			Acceptable Yes or No
6.1 Airflow is unidirectional per FDA definition - An airflow moving in a single direction, in a robust and uniform manner, and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.			
6.1.1 Smoke test observations were of flow within the DCA			
6.2 Verify ISO 5 conditions inside the DCA via particle counts.			

Reviewed by: _____ Date: _____

Persons signing as reviewers of individual test pages have determined that the results are acceptable or that no further action is necessary on a given test, and that the test form has been properly completed.